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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/335,363	06/17/1999	GEORGE SHIBATA	39D-1884	6398

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EXAMINER

BEX, PATRICIA K

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 02/26/2003

22

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application N .

09/335,363

Applicant(s)

SHIBATA ET AL.

Examiner

P. Kathryn Bex

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 20 December 2002.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-14 and 20-27 is/are rejected.
- 7) ☒ Claim(s) 15-19 and 28-34 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All   b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 20, 2002 has been entered.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

drop 3. Claims 27-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 27, line 2 recites the limitation "the belt". There is insufficient antecedent basis for this limitation in the claim. For examination purposes, it has been assumed that this claim should depend from claim 26 which defines the continuous transport mechanism as a belt. Correction is required.

### ***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an

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international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1-11, 13-14, 20-27 are rejected under 35 U.S.C. 102(e) as being anticipated by Stylli *et al* (USP 5,985,214).

Stylli *et al* teach an automated analyzer system comprising a storage and retrieval module that receives and stores a plurality of primary chemical plates in a storage means 300 (e.g. primary sample tubes). This storage and retrieval module includes a carriage mechanism 130 which grips the primary chemical plate (column 11, line 59- column 12, line 3, column 19, lines 20-column 20, line 19 Fig. 3) and transfers the primary chemical plate to a continuous, bi-directional sample transporter 310 (e.g. continuous transport) which is operably connected to a sampling distribution station. Note: the sample transport can include a plurality of conveyor means or articulated robotic arms used to grip the plates (column 17, lines 46-60, column 23, lines 12-18). Moreover, the bi-directional sample transport 310 can return the chemical plates back to the storage and retrieval unit. The sample distribution station includes a plurality sampling probes to transfer a volume of sample from the primary chemical plate 34 to a secondary, daughter multiwell plate, (e.g. secondary sample tube) with a higher density (column 12, lines 4-64). The sample distribution station can be mechanically linked to a plurality of reaction modules or workstations (e.g. first and second analyzers) (column 17, lines 60-67). Stylli *et al* teach the use of a plurality lift and transfer mechanisms 315 (e.g. tube transfer stations) adapted to move the sample plates from the sample transport mechanism to one of the plurality of reaction modules or workstations (column 20, lines 20-33). Stylli *et al* teach the use of a supervisory controller for receiving sample identification information and issuing a sample testing procedure such that the instrument is capable of performing different assays, each of

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such assays having different protocols (column 28, line 49-column 36, lines 67). Each chemical in the master table is also represented in an aliquots table 607. The creation of aliquots from any chemical managed by the system may be in any format and is not limited to multi-well plates. A chemical may be individually tracked, or become part of a master configuration where it is present with a plurality of other chemicals, in which case the group, rather than a single chemical can be tracked by the system. Each tracked entity (e.g., work unit) is recorded as an entry in format table 608. The current location of each tracked entity is stored along with its identification in the table that represents that entity. Typical formats can include tubes and bottles of various capacities, arrays of wells as in the various multi-well plates, or any other format desired. Any chemical or group of chemicals stored in a format can be identified, e.g., by a unique bar code label (column 30, lines 42-59).

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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8. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stylli *et al* (USP 5,985,214) in view of Kurosaki *et al* (USP 5,587,129).

Stylli *et al* as discussed previously, do teach the creation of aliquots from any chemical managed by the system may be in any format and is not limited to multi-well plates. Typical formats can include tubes and bottles of various capacities, arrays of wells as in the various multi-well plates, or any other format desired. However, Stylli *et al* fail to specifically recite a sample probe comprising a cap piercer for removing liquid from the primary sample without removing the cap from the primary sample tube. However, the use of cap piercing probes is considered conventional in the art, see Kurosaki *et al*. Kurosaki *et al* teach an automatic analyzer which comprises a probe 12 for aspirating part of a sample from a sample tube 4 and dispensing into a reaction tubes 8 (column 3, line 62- column 4, line 7).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have incorporated in the system of Stylli *et al* the piercing probe, as taught by Kurosaki *et al*, in order to aspirate the contents of the sample vial without exposing the sample to possible environmental contaminants.

#### ***Response to Arguments***

9. Applicant's arguments with respect to claims 1-34 have been considered but are moot in view of the new ground(s) of rejection. See above Office Action.

#### ***Allowable Subject Matter***

10. Claims 15-19, 33-34 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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11. Claims 28-32 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

12. The following is a statement of reasons for the indication of allowable subject matter: the instant claims are drawn to a clinical chemistry system which includes a storage station, a sampling station with sample probe, a carriage mechanism for gripping a primary tube and providing it to the sampling station. Additionally, the system includes a first and second secondary tube transfer means for removing the secondary tubes from the continuous transport means and providing the secondary tubes to a corresponding analyzer. While numerous of such clinical analyzer systems exist, none of the prior art teaches a clinical chemistry system which includes; a storage station, a sampling station with sample probe, a carriage mechanism for gripping a primary tube and providing it to the sampling station, a first and second secondary tube transfer means for removing the secondary tubes from the continuous transport means and providing the secondary tubes to a corresponding analyzer. The continuous transport means comprising a continuous belt and a plurality of secondary tube carriages mounted to the belt which are adapted for carrying the secondary tube and provides lateral access to the secondary tube from at least two sides.

### ***Conclusion***

13. Claim 15-19, 28-34 are objected to. Claims 1-14, 20-27 are rejected.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to P. Kathryn Bex whose telephone number is (703) 306-5697. The examiner can normally be reached on Mondays-Thursdays, alternate Fridays from 6:00 am to

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3:30 pm EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 308-4037.

The fax number for the organization where this application or proceeding is assigned is (703) 872-9310 for official papers prior to mailing of a Final Office Action. For after-Final Office Actions use (703) 872-9311. For unofficial or draft papers use fax number (703) 305-7719. Please label all faxes as official or unofficial. The above fax numbers will allow the paper to be forwarded to the examiner in a timely manner.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0661.

*Kathryn Bex*

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Patent Examiner  
AU 1743  
February 20, 2003

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